



**UNITED STATES DEPARTMENT OF COMMERCE**  
**United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

#15  
ew

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/184,418 11/02/98 HAHN

B 3532-4000

MORGAN & FINNEGAN  
345 PARK AVENUE  
NEW YORK NY 10154

HM12/0705

EXAMINER

ZEMAN, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/05/01

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/184,418

Applicant(s)

Hahn et al.

Examiner

Robert A. Zeman

Art Unit

1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 2, 1998
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above, claim(s) 7-9, 11-13, 15-32, and 35-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, 14, 33, and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-41 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

Art Unit: 1645

## **DETAILED ACTION**

### ***Election/Restriction***

It is noted that a restriction/election of species was previously made in Paper No. 11 mailed on 12-5-2000; however, on review and reconsideration of the entire record and in accordance with current Office practice, the requirement is revised as follows:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:1 and kits containing the same, classified in class 536, subclass 23.72.
2. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:2 and kits containing the same, classified in class 536, subclass 23.72.
3. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:3 and kits containing the same, classified in class 536, subclass 23.72.
4. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:4 and kits containing the same, classified in class 536, subclass 23.72.
5. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:5 and kits containing the same, classified in class 536, subclass 23.72.
6. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:6 and kits containing the same, classified in class 536, subclass 23.72.
7. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:7 and kits containing the same, classified in class 536, subclass 23.72.

Art Unit: 1645

8. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:8 and kits containing the same, classified in class 536, subclass 23.72.
9. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:9 and kits containing the same, classified in class 536, subclass 23.72.
10. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:10 and kits containing the same, classified in class 536, subclass 23.72.
11. Claims 1-6, 10, 14 and 33-34, drawn to nucleic acids represented by SEQ ID NO:11 and kits containing the same, classified in class 536, subclass 23.72.
12. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:1, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
13. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:2, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
14. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:3, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.

Art Unit: 1645

15. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:4, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
16. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:5, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
17. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:6, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
18. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:7, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
19. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:8, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.

Art Unit: 1645

20. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:9, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
21. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:10, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
22. Claims 7-9, 11-13 and 15-21, drawn to polypeptides encoded by SEQ ID NO:11, vectors encoding said peptides, cells containing said vectors and method for expressing said vector, classified in class 530, subclass 350 and class 435, subclass 69.1+.
23. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:1 and kits containing same, classified in class 530, subclass 388.35.
24. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:2 and kits containing same, classified in class 530, subclass 388.35.
25. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:3 and kits containing same, classified in class 530, subclass 388.35.
26. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:4 and kits containing same, classified in class 530, subclass 388.35.

Art Unit: 1645

27. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:5 and kits containing same, classified in class 530, subclass 388.35.
28. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:6 and kits containing same, classified in class 530, subclass 388.35.
29. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:7 and kits containing same, classified in class 530, subclass 388.35.
30. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:8 and kits containing same, classified in class 530, subclass 388.35.
31. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:9 and kits containing same, classified in class 530, subclass 388.35.
32. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:10 and kits containing same, classified in class 530, subclass 388.35.
33. Claims 23, 25, 29-30 and 35, drawn to antibodies with specificity for SEQ ID NO:11 and kits containing same, classified in class 530, subclass 388.35.
34. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:1, classified in class 424, subclass 208.1.
35. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:2, classified in class 424, subclass 208.1.

Art Unit: 1645

36. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:3, classified in class 424, subclass 208.1.
37. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:4, classified in class 424, subclass 208.1.
38. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:5, classified in class 424, subclass 208.1.
39. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:6, classified in class 424, subclass 208.1.
40. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:7, classified in class 424, subclass 208.1.
41. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:8, classified in class 424, subclass 208.1.
42. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:9, classified in class 424, subclass 208.1.
43. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:10, classified in class 424, subclass 208.1.
44. Claims 22 and 24, drawn to methods of inducing antibodies (immunizing) with specificity for SEQ ID NO:11, classified in class 424, subclass 208.1.
45. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:1, classified in class 435, subclass 5.



Art Unit: 1645

46. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:2, classified in class 435, subclass 5.
47. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:3, classified in class 435, subclass 5.
48. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:4, classified in class 435, subclass 5.
49. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:5, classified in class 435, subclass 5.
50. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:6, classified in class 435, subclass 5.
51. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:7, classified in class 435, subclass 5.
52. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:8, classified in class 435, subclass 5.
53. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:9, classified in class 435, subclass 5.
54. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:10, classified in class 435, subclass 5.
55. Claims 26-27, drawn to methods of detecting HIV-1 using antibodies with a specificity for SEQ ID NO:11, classified in class 435, subclass 5.

Art Unit: 1645

56. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:1, classified in class 435, subclass 6.
57. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:2, classified in class 435, subclass 6.
58. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:3, classified in class 435, subclass 6.
59. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:4, classified in class 435, subclass 6.
60. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:5, classified in class 435, subclass 6.
61. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:6, classified in class 435, subclass 6.
62. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:7, classified in class 435, subclass 6.
63. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:8, classified in class 435, subclass 6.
64. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:9, classified in class 435, subclass 6.
65. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:10, classified in class 435, subclass 6.

Art Unit: 1645

66. Claims 31-32 and 37, drawn to methods of detecting HIV-1 using nucleic acid hybridization of SEQ ID NO:11, classified in class 435, subclass 6.
67. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:1, classified in class 536, subclass 24.32.
68. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:2, classified in class 536, subclass 24.32.
69. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:3, classified in class 536, subclass 24.32.
70. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:4, classified in class 536, subclass 24.32.
71. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:5, classified in class 536, subclass 24.32.
72. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:6, classified in class 536, subclass 24.32.
73. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:7, classified in class 536, subclass 24.32.
74. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:8, classified in class 536, subclass 24.32.

Art Unit: 1645

75. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:9, classified in class 536, subclass 24.32.
76. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:10, classified in class 536, subclass 24.32.
77. Claims 36 and 39, drawn to nucleic acid probes comprising fragments of SEQ ID NO:11, classified in class 536, subclass 24.32.
78. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:1, classified in class 435, subclass 5.
79. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:2, classified in class 435, subclass 5.
80. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:3, classified in class 435, subclass 5.
81. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:4, classified in class 435, subclass 5.
82. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:5, classified in class 435, subclass 5.
83. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:6, classified in class 435, subclass 5.
84. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:7, classified in class 435, subclass 5.

Art Unit: 1645

85. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:8, classified in class 435, subclass 5.
86. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:9, classified in class 435, subclass 5.
87. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:10, classified in class 435, subclass 5.
88. Claim 28, drawn to method of detecting antibodies using polypeptides encoded by SEQ ID NO:11, classified in class 435, subclass 5.
89. Claim 38, drawn to method of detecting HIV-1 using PCR, classified in class 435, subclass 91.2.
90. Claims 40-41, drawn to methods of comparing sequences, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-33 and 67-77 are separate and distinct from each other as they comprise completely differing biochemical and physical entities having differing properties and uses.

Inventions 1-11 are drawn to nucleic acids, whereas Invention 12-22 are drawn to polypeptides, Inventions 23-33 to antibodies and Inventions 67-77 to probes.

Inventions 1-11 are separate and distinct from Inventions 34-44 as the substances of Inventions 1-11 cannot be used in the methods of Inventions 34-44.

Art Unit: 1645

Inventions 12-22 are each related to Inventions 34-44 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Inventions 12-22 can be used in other methods such as binding studies.

Inventions 34-44 are each related to Inventions 23-33 as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies of Inventions 23-33 can made synthetically or isolated from their natural source.

Inventions 1-22 are each separate and distinct from Inventions 45-55 as the substances of Inventions 1-22 cannot be used in the methods of Inventions 45-55.

Inventions 23-33 are each related to Inventions 45-55 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Inventions 23-33 can be used in other methods such as anti-idiotypic antibody production and affinity purification.

Art Unit: 1645

Inventions 34-44 are each separate and distinct from Inventions 45-55 as they are drawn to differing methods having different steps and leading to differing results.

Inventions 12-33 are each separate and distinct from Inventions 56-66 as the substances of Inventions 12-33 cannot be used in the methods of Inventions 56-66.

Inventions 1-11 are each related to Inventions 56-66 as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acids of Inventions 1-11 can be used in other methods such as polypeptide production.

Inventions 34-66 are each separate and distinct from each other as they are drawn to differing methods having different steps and leading to differing results.

Inventions 34-66 are each separate and distinct from Inventions 67-77 as the probes of Inventions 67-77 cannot be used in the methods of Inventions 34-66.

Inventions 67-77 are each separate and distinct from Inventions 78-88 as the nucleic acid probes of Inventions 67-77 cannot be used in the methods of Invention 78-88.

Inventions 1-33 and 67-77 are separate and distinct from Invention 89 as the substances of Inventions 1-33 and 67-77 cannot be used in the methods of Invention 89.

Inventions 34-66 are each separate and distinct from Inventions 78-89 as they are drawn to differing methods having different steps and leading to differing results.

Art Unit: 1645

Inventions 1-33 and 67-77 are each separate and distinct from Invention 90 as the substances of Inventions 1-33 and 67-77 cannot be used in the methods of Invention 90.

Inventions 34-66 are each separate and distinct from Inventions 78-90 as they are drawn to differing methods having different steps and leading to differing results.

During a telephone conversation with Benjamin A. Adler, Ph.D., J.D. on 6-27-2001 a provisional election was made with traverse to prosecute the invention of Group 8, claims 1-6, 10, 14 and 33-34 (i.e. SEQ ID NO:8). Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-6, 9-10, and 14, in so far as drawn to the subject matter than SEQ ID NO:8 and claims 7-9, 11-13, 15-32 and 35-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

Claim 3 is objected to because of the following informalities: Claim 3 contains an obvious grammatical error. "a LTR" should read "an LTR" Appropriate correction is required.

Claims 1-6, 10, 14 and 33-34 are objected to as reciting non-elected material.



Art Unit: 1645

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The aforementioned claims are drawn to pharmaceutical compositions. The specification, however, is silent on how such a composition would be used and equally silent on the efficacy of said compositions. People of skill in the art require documented factual evidence that a benefit can be derived by the therapeutic application of a substance. The instant specification fails to provide evidence that the claimed pharmaceutical compositions would elicit any type of beneficial therapeutic response. Since no evidence has been provided that illustrates or even suggests that the claimed pharmaceutical compositions are capable of eliciting a beneficial therapeutic response, one of skill in the art would not be able to make and use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1645

Claims 1-3, 5-6, 10, 14 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 are confusing in referring to a figure since it is not clear which nucleic acids are being claimed.

Claims 2-3 and 5 are rendered vague and indefinite by the use of the term "derived". It is unclear what is meant by said term. Does said derivation require some chemical modification or other process? As written, it is impossible to determine the metes and bounds of the claimed invention.

### *Conclusion*

No claim is allowed.

SEQ ID NO:8 is free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.



DONNA WORTMAN  
PRIMARY EXAMINER

Robert A. Zeman

June 28, 2001